



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 74

[Docket No. FDA-2011-C-0050]

D&C Red No. 6 and D&C Red No. 7; Change in Specification; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of August 7, 2012, for the final rule that published in the Federal Register of July 6, 2012 (77 FR 39921) and that revised the requirements for D&C Red No. 6 and D&C Red No. 7 by replacing the current specification for “Ether-soluble matter” with a maximum limit of 0.015 percent for the recently identified impurity 1-[(4-methylphenyl)azo]-2-naphthalenol.

DATES: Effective date confirmed: August 7, 2012.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In the Federal Register of July 6, 2012, FDA amended the color additive regulations in §§ 74.1306 and 74.1307 (21 CFR 74.1306 and 74.1307) by

replacing the current specification for “Ether-soluble matter” with a maximum limit of 0.015 percent for the recently identified impurity 1-[(4-methylphenyl)azo]-2-naphthalenol. FDA also removed Appendix A in 21 CFR part 74, which pertains to the ether-soluble matter specification. The changes to §§ 74.1306 and 74.1307 also affect the color additive regulations in §§ 74.2306 and 74.2307 (21 CFR 74.2306 and 74.2307) because the identity and specifications in §§ 74.1306 and 74.1307 are referenced by §§ 74.2306 and 74.2307.

FDA gave interested persons until August 6, 2012, to file objections or requests for a hearing. The Agency received no objections or requests for a hearing on the final rule. Therefore, FDA finds that the effective date of the final rule that published in the Federal Register of July 6, 2012, should be confirmed.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, and redelegated to the Director, Office of Food Additive Safety, notice is given that no objections or requests for a hearing were filed in response to the July 6, 2012, final rule. Accordingly, the amendments issued thereby became effective August 7, 2012.

Dated: September 5, 2012.

Dennis M. Keefe,

Director,

Office of Food Additive Safety,

Center for Food Safety and Applied Nutrition.